

K251910 Focal One®Nov 19, 2025
152 days to decisionK251910 · Product code: **PLP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Intensity Ultrasound System For Prostate Tissue Ablation (PLP)
Date received	Jun 20, 2025
Decision date	Nov 19, 2025
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edap Technomed, Inc.
Location	Norcross, GA, US
Contact	Hugo Embert
510(k) history	5 submissions · 5 cleared · 2001-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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